

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

John F. SHANLEY *et al.*

Application No.: 10/777,283

Filing Date: February 11, 2004

For: IMPLANTABLE MEDICAL DEVICE  
WITH BENEFICIAL AGENT  
CONCENTRATION GRADIENT

Art Unit: 1615

Examiner: Eric E. SILVERMAN

Attorney Ref. No.: P067

Confirmation No.: 5462

**RESPONSE UNDER 37 C.F.R. §§ 1.111, 1.116**

**Mail Stop AF**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated November 15, 2006, which set a 3-month shortened statutory period for response thereto, favorable reconsideration, reexamination, and allowance of this patent application are respectfully requested in view of the following remarks. A Petition for a one-month extension of time, and the applicable fee, is filed on even date herewith.

***Personal Interview***

Applicant and the undersigned wish to thank Mr. Woodward and Dr. Silverman for the courteous and productive interview conducted on March 6, 2007, with Ms. Shelly Guest Cermak and Mr. Adam Cermak, the Applicant's local counsel for this application. Because Applicant was not relieved of the duty under 37 C.F.R. § 1.133(b) of providing a summary of the arguments presented during that interview, Applicant provides the following comments.

Mr. Woodward first asked Ms. Cermak and Mr. Cermak were 'of record' in this

application. Applicant notes that a duly-executed Authorization to Act in a Representative Capacity, signed by the undersigned and providing the requisite authority to Ms. Cermak and Mr. Cermak, was made of record on March 6, 2007.

Ms. Cermak began the interview by discussing the rejections under 35 U.S.C. § 112, first and second paragraphs, of Claim 34. Ms. Cermak directed Dr. Silverman's and Mr. Woodward's attentions to the paragraphs of the specification identified in the last Amendment, in which the term "barrier" was used and explained. Mr. Cermak added some explanation of the structure of a stent, with reference to Figs. 2 and 3 of this application, and how the barrier functions to inhibit drug from moving radially inward (luminally), and thus directs drug radially outward (murally) when *in situ*. At the conclusion of Ms. Cermak's presentation, Mr. Woodward stated that these rejections would be withdrawn.

Mr. Cermak then addressed the rejection of Claim 21 *et seq.* under 35 U.S.C. § 102 over U.S. Patent No. 5,624,411, issued to Tuch. Mr. Cermak began by pointing out that Claim 21 was the only independent claim, and included a combination of manipulative steps including "introducing the . . . solution into the at least one recess". Mr. Cermak noted that the Office Action pointed to Figs. 4a and 4b of *Tuch* when it alleged that the prior art identically described this step of the claim. Mr. Cermak then explained that he had, that morning, read all of *Tuch*, including a review of the three patents incorporated by reference at column 2 thereof, and could find no mention of any recess in any of their disclosures.

Dr. Silverman then pointed to Figs. 4a and 4b of *Tuch* and alleged that the surface imperfections shown in the photomicrographs of those figures were 'recesses' within the meaning of this application, and further alleged that the coating processes described in *Tuch* would necessarily fill those imperfections. Mr. Cermak responded that, indeed, *Tuch* shows surface imperfections, but that essentially nothing is absolutely smooth at the smallest scale; instead, these imperfections are not recesses within the meaning of this application, and one of ordinary skill would not read the claim term "recess" to read on a surface imperfection of a stent.

In response to this line of argument, Mr. Woodward stated that the rejection under section

102 would also be withdrawn when a response to the Office Action, presenting these arguments in writing, was filed.

***Rejections under 35 U.S.C. § 112, first and second paragraphs***

In the Office Action, beginning at page 2, Claim 34 was again rejected under 35 U.S.C. § 112, first paragraph, as reciting subject matter that allegedly fails to comply with the written description requirement, and under 35 U.S.C. § 112, second paragraph, as reciting subject matter that allegedly is indefinite. Applicant respectfully requests reconsideration of these rejections, in view of the explanation provided during the personal interview conducted on March 6<sup>th</sup> and the indication by Mr. Woodward that this rejection would be withdrawn.

***Rejection under 35 U.S.C. § 102***

In the Office Action, beginning at page 4, Claims 21-27, 29-37, and 48 were again rejected under 35 U.S.C. § 102, as reciting subject matters that allegedly are anticipated by *Tuch*. Applicant respectfully requests reconsideration of this rejection, in view of the explanation provided during the personal interview conducted on March 6<sup>th</sup> and the indication by Mr. Woodward that this rejection would be withdrawn.

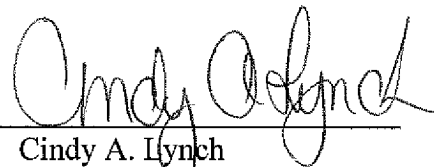
***Conclusion***

For at least the foregoing reasons, Applicant respectfully submits that this patent application is in condition for allowance. An early indication of the allowability of the application is therefore respectfully solicited.

If Dr. Silverman believes that a telephone conference with the undersigned would expedite passage of the present patent application to issue, he is invited to call on the number below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. If, however, additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is hereby authorized to charge fees necessitated by this paper, and to credit all refunds and overpayments, to our Deposit Account 50-3100.

Respectfully submitted,

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